## REMARKS

The Office Action of January 20, 2010, has been carefully studied. Claims 1, 3-6, 8, 11, 12 and 19-27 currently appear in this application. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration and formal allowance of the claims.

## Claim Amendments

The claims have been amended to recite that the recombinant protein is a soluble protein. Support for this amendment can be found throughout the specification, as the specification and claims are drawn to stabilizing protein solutions. If the protein is in solution, by definition the protein is soluble.

## Art Rejections

Claims 1, 3, 4, 11, 12, 19-21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al., *Biotechnology Techniques* (1997) in light of support by Goldfarb et al., *Units for Magnetic Properties* (1985) and mindat.org (Magnetite Mineral Information).

This rejection is respectfully traversed.

It is respectfully submitted that Mehta has nothing at all to do with the herein claimed method. What is claimed herein is a method for stabilizing a protein solution by storing the protein solution under the influence of a magnetic field. As described in the specification at page 1, line 20 to page 2, line 14, most physiologically active proteins are known to be associated in an aqueous solution, which is the major cause of reducing stability of these proteins in solution. Conventionally, these proteins are provided in lyophilized form or are provided in the form of solutions supplemented with various additives for improving the stability of the solution. Unfortunately, very complex processes are required to remove contaminants from the stabilizers, such as viruses, making stabilized solutions undesirable. The process claimed herein is for stabilizing a protein solution by maintaining the protein in solution under the influence of a magnetic field.

Mehta, however, merely discloses that a protein, such as an antibody, that is bound to magnetic particles such as magnetite particles. That is, Mehta binds the protein to magnetic particles, which particles can be used for radioimmunoassay, enzyme immobilization and in affinity chromatography. There is nothing in Mehta that even suggests that the magnetite particles stabilize a protein solution. In fact, by binding the

proteins to the magnetic particles, the proteins are essentially removed from solution. Moreover, in the last paragraph on page 296, Mehta specifically states, "Further study to determine the shabbily and limitations of the method for immobilizing cells as well as enzymes is warranted." That is, Mehta merely binds the proteins to magnetic particles, but does not know if this provides stability to the proteins, or if the protein-particle entities are stable.

Accordingly, one skilled in the art reading Mehta along with Goldfarb and magnetite mineral information would not expect that the addition of magnetic particles to a solution of protein, in which the proteins are bound to the magnetic particles and thus removed from solution, would lead one to store a solution of proteins under a magnetostatic field in order to maintain the stability of the protein solution.

Claims 1, 3, 4, 11, 12, 19-21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerdan et al., *Magnetic Resonance in Medicine*, 1989.

This rejection is respectfully traversed.

The proteins in the present method remain in solution when they are exposed to a magnetostatic field. In contrast thereto, the proteins in Cerdan are immobilized on magnetite beads. That is, these proteins are

removed from solution by virtue of their being immobilized on the beads. As discussed *supra*, the proteins in Cerdan are removed from solution, while the proteins in the present method remain in solution. There is nothing in Cerdan that would lead one skilled in the art to maintain proteins in solution and expose the solution to a magnetic field in order to stabilize the solution. The particles in Cerdan are removed from solution.

Claims 1, 3, 4, 5, 6, 8, 11, 12 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerdan as applied above and further in view of Skibell et al., *Blood*, 2001.

This rejection is respectfully traversed.

As noted above, the present method stabilizes a protein solution. That is, the protein is dissolved in the solvent. Cerdan removes the proteins from solution by coating magnetite beads with the proteins. These magnetite beads are not soluble, which means that the proteins are no longer in solution. Skibell adds nothing to Cerdan, because Skibell merely teaches that EPO bound to magnetic beads will inherently have a naggnetostatic field.

Cerdan teaches that proteins can be bound to magnetite beads on order to produce contrast agents in MRI imaging of tumors. There is absolutely nothing in Cerdan that even suggests adding magnetite to a

solution of proteins to provide a magnetostatic field in order to prevent protein aggregation or association. Cerdan removes the proteins from solution by coating them onto magnetite particles. Skibell adds nothing to Cerdan, because Skibell is concerned with immunoassays, not with stabilizing protein solution.

None of the cited references has anything to do with maintaining proteins in solution in a stable form. All of the cited references teach immobilizing proteins on magnetic particles. There is nothing in any of the cited references that would lead one skilled in the art to maintain a protein solution under the influence of a magnetostatic field, with the proteins in solution, in order to stabilize the proteins. In the method claimed herein, the proteins remain in solution. In the cited references, the proteins are all removed from solution.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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